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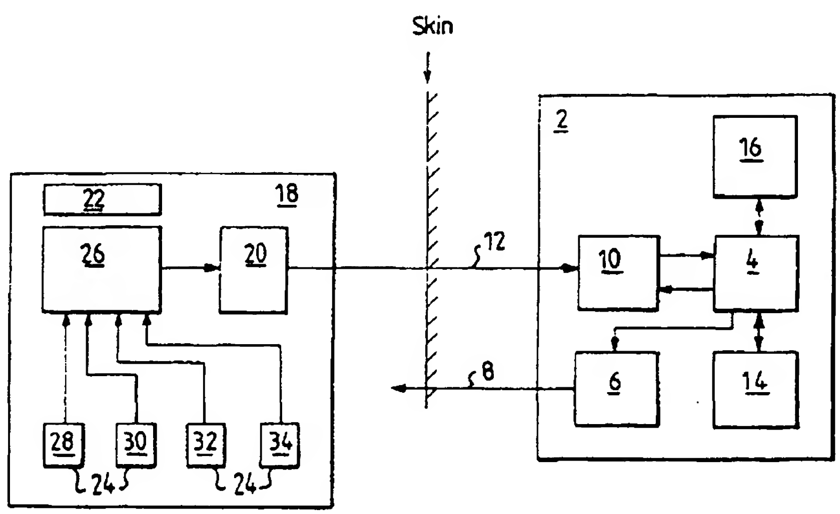
(54) Title: MEDICAL IMPLANT




(57) Abstract

The invention relates to a medical implant (2), e.g. a heart stimulator, comprising a detecting means (10) adapted to detect an extracorporeally generated interrogation signal (12) related to at least one predetermined working parameter of said implant. Said interrogation signal (12) is generated by an interrogation signal generating device (18) adapted for one-way signaling to the medical implant (2). The implant comprises a response signal generator means (6) adapted to generate an extracorporeally detectable, e.g. by a stethoscope, response signal (8) indicating if the relevant working parameter has a satisfactory or non-satisfactory value in response to a detected interrogation signal.

# Medical implant

## Field of the invention.

The invention relates to a medical implant according to the preamble of claim 1 and an interrogation signal generating device according to the preamble of claim 9 adapted to work with said medical implant.

## Background of the invention.

In a normal follow-up for a pacemaker patient many different working parameters of the pacemaker are tested, e.g. battery status, stimulation threshold, electrode lead impedance and others. The follow-up is made in a hospital at least once per year and the physician uses a bi-directional communication programmer that communicates with the pacemaker by radio waves. The requested information is received by the programmer and analyzed by the physician, which is a difficult and time-consuming job. The programmer is quite expensive and then not always a part of the ordinary equipment for every small-sized hospital.
Battery tests can also be performed by putting a magnet over the pacemaker that changes the stimulation rate in dependence of the battery status. This rate can be seen on an ECG machine or by listening or feeling the pulse. Devices used for performing battery tests are for instance disclosed in US-4,390,020 and US-4,416,282.
In US-4,390,020 a programmable pacemaker is disclosed capable of operating in several stimulating modes, having battery powered stimulating means and stimulating mode selector means. Sensing and evaluating means, which can be activated externally by means of a magnet, for example at a medical examination, monitor the terminal voltage of the battery and cause the pacemaker via the stimulating selector

means to change operation from a first stimulating mode with a programmed stimulation rate to a mode with a fixed stimulation rate, when the terminal voltage decreases below a first threshold value and operate in a second predetermined stimulating mode at a fixed stimulation rate when the terminal voltage decreases below the first and a lower second threshold value.

US-4,416,282 discloses a similar pacemaker which also includes sensing and evaluating means for monitoring of the battery capacity with regard to two battery depletion levels. The stimulation rate automatically decreases with the decreasing of the battery capacity below the depletion levels.

In US-4,488,555 a battery condition warning system for a medical implant is known. The warning system generates an audible alarm to warn the patient of an impending battery failure.

In US-4,614,192 an implantable cardiac defibrillator is disclosed, providing, upon magnet-type interrogation, an audible indication to verify the status of the implanted device. To enable the defibrillator to deliver a defibrillating pulse a control circuit must be placed in an active state. To place it in an active state a ring magnet is used to toggle a status flip-flop that asserts an enabling signal to the control circuit. At the same time, an audio oscillator is energized by the output signal from said status flip-flop and from a rate circuit, enabling the audio oscillator to emit sounds synchronous with the heart beat if a bipolar electrode is properly positioned within the heart and to emit a continuous tone if the defibrillator is inactive and properly positioned. Absence or presence of an audible tone indicates whether the probe is properly lodged about the right ventricle. The audible indication in the defibrillator disclosed in US-A-4,614,192 is generated in

response of a magnet interrogation and reflects the status of the implant at the time the interrogation is made, i.e. the measurement procedure is performed at that time.

One drawback for many of these known solutions is that some kind of more or less complicated technical equipment is needed, e.g. a programmer or an ECG-machine, not always available in smaller clinics.
Another drawback is that prior the implant can respond to an interrogation from an external device, often time-consuming tests has to be performed by the implant.

The object of the invention is to provide a medical implant capable of immediately generating an response signal that is easy to recognize outside the body by e.g. a stethoscope, and that reflects the present status of at least one predetermined working parameter of the implant. Another object is that the response signal indicates if the working parameter has a satisfactory value or not.
One further object of the invention is to provide an interrogation signal-generating device adapted to work with said medical implant.

<u>Short description of the inventive concept.</u>

These objects are achieved in that the medical implant, according to the preamble of the appended claim 1, is provided with features set forth in the charcterizing part of claim 1. Furthermore, the interrogation signal generating device, according to the preamble of the appended claim 9, is provided with features set forth in the charcterizing part of claim 9.

Preferred embodiments are set forth in the dependent claims.

<u>Short description of the appended drawing.</u>

The FIGURE shows a block diagram of the medical implant and the interrogation signal generating device according to the invention.

Detailed description of preferred embodiments of the invention.

In the FIGURE the medical implant 2 and the interrogation signal generating device 18 are shown in a block diagram. The medical implant 2, e.g. a pacemaker or a defibrillator, comprises a first control means 4 connected to a response signal generator means 6, a detecting means 10, working parameter status registers 14 and a test means 16. The person skilled in the art realizes that the medical implant 2 also includes inter alia an energy source, one or many electrode leads for applying stimulation pulses to the tissue etc. However, for sake of simplicity these features are not described in detail neither in the figure nor in the description since they are not an inherent part of the invention and their functions are well known to persons skilled in the art.

The interrogation signal generating device 18 includes only a signal generator 20 adapted to generate an interrogation signal 12, an energy source 22, select means 24 with a predetermined number of activation buttons 28, 30, 32, 34 (four in the figure) and a second control means 26. Each activation button represents at least one working parameter of said medical implant. The working parameters could be e.g. the battery status, the status of lead impedance or the status of a stimulation threshold. One of the activation buttons represents the overall status of all working parameters together.

The medical implant 2 and the interrogation signal generating device 18 work together in the following way: The person who is going to interrogate the implant 2 places the device 18 on the skin of a patient above the implant, presses one of the activation buttons and thereby causing

the second control means 26 to activate said signal generator 20 to generate an interrogation signal 12. The working parameter represented by the pressed activation button is univocally identified by the generated interrogation signal 12.

The interrogation signal is preferably a radio-wave signal having a frequency in the range 2-8 kHz. A predetermined communication protocol is used enabling said univocal identification of the interrogation signal.

According to an alternative embodiment the interrogation signal is a magnetic signal. Interrogation is then made by placing a device capable of generating magnetic field of a predetermined kind, e.g. a magnet, on the skin close to the implant.

The interrogation signal 12 is detected by the detecting means 10 in the medical implant 2. According to a preferred embodiment the telemetry coil, normally used for ordinary communication between an external programming device and a medical implant, is used for detecting the interrogation signal 12. Since this technique is well known to the person skilled in the art it will not be described here.

The detected interrogation signal 12 is applied to the first control means 4 which addresses the working parameter status register 14 that matches the requested working parameter. The content of the addressed status register is read by said first control means 4 which then activates the response signal generator 6 to generate a response signal 8 which is detectable outside the body of the implant wearer.

According to a first preferred embodiment the response signal 8 is an acoustic signal generated by an acoustic signal generating means, e.g. a piezoelectric crystal. The frequency of the generated acoustic tone could be in the range of 100-1900 Hz, preferably 1000-1900 Hz where 1400 Hz is a preferred value. The tone should be strong enough to be able to be detected by a stethoscope placed on the skin close to the implant. When an interrogation signal is

detected by the detection means 10 the first control means 4 identifies the working parameter status register requested by said interrogation signal. The value, "satisfactory" or "non-satisfactory", in the requested register is read out by said first control means 4 and the response signal generator 6 is activated to generate the response signal 8, in this embodiment an acoustic signal. The response signal generator is preferably active during 5 minutes and generates a response signal every 15$^{th}$ second. The response signal 8 representing the states "satisfactory" or "non-satisfactory" can of course be chosen in many different ways, e.g. "satisfactory" could be represented by five short tones followed by five long tones, and "non-satisfactory" could be represented by the sequence three short tones, three long tones and three short tones.

According to a second preferred embodiment the response signal 8 is represented by a predetermined change of the stimulation frequency. This change in frequency can be palpated directly, detected by a stethoscope or studied on a print-out from an ECG-equipment.
When, according to this second preferred embodiment, an interrogation signal is detected by the detection means 10, the first control means 4 changes, if necessary, the pacing mode to VOO, that is ventricular stimulation with no sensing and no inhibition possible, and the stimulation rate to a predefined rate related to the state of the interrogated working parameter. The state "satisfactory" could e.g. be represented by a stimulation rate per minute of 100 and the state "non-satisfactory" could then be represented by a rate of 80.
If the interrogation signal is a radio-wave signal this predefined rate preferably could last for e.g. 32 pacing intervals and if the interrogation signal is a magnetic signal, as long as the magnetic field is present.

By continuously updating the working parameter status registers 4 the response signal can be generated almost immediately because no time-consuming tests of the different working parameters has to be performed. The working parameters of the medical implant could be, as indicated above, e.g. the battery status, the status of lead impedance or the status of the stimulation threshold. One of the activation buttons represents the overall status of all working parameters together.

The most common used battery in modern pacemakers is the lithium-iodine battery. As current is drained from the battery an increase in the internal impedance of the battery occurs. Since the rate of increase in battery impedance versus time at any specific battery current drain is known, measured battery current drain and battery impedance allow prediction of remaining device longevity. In practice, the internal impedance is measured at regular intervals, e.g. every 24$^{th}$ hour, and compared to a predetermined threshold representing an impedance value corresponding to the recommended replacement time (RRT), being e.g. 2 years. The battery status is given the state "satisfactory" if the RRT is more than e.g. 2 years and the state "non-satisfactory" if less than 2 years.

A very vital part of a pacemaker system is the electrode lead connecting the pacemaker to the inside of the heart. The electrode lead is inserted into the heart via e.g. a great vein and comprises an electrical lead insulated by e.g. silicone. The function of an electrode lead can be tested, by measuring of the lead impedance. If the lead impedance is decreased, it can be caused by a breakdown or damage in the insulation of the lead, and if the lead impedance is increased it can be caused by a break or damage of the electrical lead. The lead impedance can be measured e.g. by an lead impedance scanning system disclosed in US-4,899,750. In this system the voltage difference over a sample capacitor, before and after the delivery of a pacing

pulse, is used in an equation to calculate the lead impedance. If the lead impedance is in the range of e.g. 750+/-500 Ohm the status of lead impedance is given the state "satisfactory" and if outside said range the state "non-satisfactory".

For the stimulation threshold, for the ventricle and/or the atrium, the state is given the value "satisfactory" if the threshold is below a predetermined value, e.g. 3 Volts and "non-satisfactory" if the threshold is above said value. It is of course only possible to test the stimulation threshold if some kind of automatic search for the stimulation threshold can be performed, e.g. according to the AUTOCAPTURE™-algorithm, at regular intervals.

All the values used to determine if the state is "satisfactory" or "non-satisfactory" for the working parameters can of course be individually set in dependence of the circumstances.

As indicated above one of the working parameter status registers reflects the combined status of all working parameters in the way that if any of the other working parameters is in the "non-satisfactory"-state the combined status will be "non-satisfactory". When the interrogation signal is a magnetic signal, in accordance with the above-mentioned alternative embodiment, the response signal reflects the content of the register with said combined status.

As indicated above the values stored in the working parameter status registers are updated continuously as a result of tests performed by said test means 16.

It is obvious to the skilled person that other working parameters than the above described can be used, e.g. if a certain level for a predetermined parameter is exceeded more than a predetermined number of times the state is set to "non-satisfactory". In general, if a predetermined event occurs (related to the heart or the pacemaker), that not

fulfills the "satisfactory"-criteria, the state for that working parameter is set to "non-satisfactory".

Claims

1. Medical implant (2), e.g. a heart stimulator, comprising a detecting means (10) adapted to detect an extracorporeally generated interrogation signal (12) related to at least one predetermined working parameter of said implant, and a response signal generator means (6) adapted to generate an extracorporeally detectable response signal (8) in response to a detected interrogation signal (12), **characterized in** that said implant comprises a predetermined number of working parameter status registers (14), each containing updated data representing a first or a second state of a working parameter,
wherein said first state represents a satisfactory value of said working parameter
and said second state represents a non-satisfactory value of said working parameter,
and that said generated response signal (8) reflects the content of a status register (14).

2. Medical implant according to claim 1 **characterized in** that each status register (14) is continuously and automatically updated at predefined intervals.

3. Medical implant according to claims 1 or 2 **characterized in** that one of the working parameters reflects the overall status of all other working parameters.

4. Medical implant according to any of the preceding claims **characterized in** that each status register is updated with said satisfactory or non-satisfactory value indicating the result of a test performed by a test means (16) for the at least one working parameter related to that status register.

5. Medical implant according to any of the preceding claims **characterized in** that said response signal (8) is acoustic.

6. Medical implant according to any of claims 1-4 **characterized in** that said response signal generator means (6) comprises stimulation means adapted to generate heart stimulation pulses to a heart via electrode leads, said stimulation pulses having a frequency, wherein said response signal (8) is represented by a predetermined change of said stimulation frequency.

7. Medical implant according to any of the preceding claims **characterized in** that said response signal is easy detectable and identified by using a stethoscope.

8. Medical implant according to any of the preceding claims **characterized in** that said interrogation signal (12) is a magnetic signal.

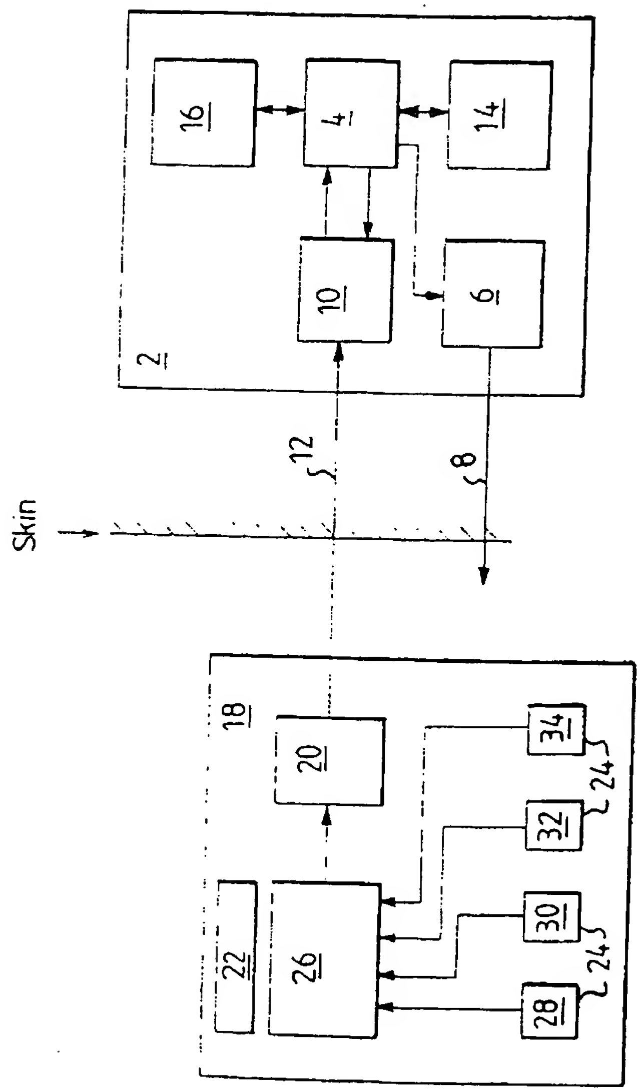
9. Interrogation signal generating device (18) adapted for one-way signaling to the medical implant (2) according to any of claims 1-7 **characterized in** that said device only comprises a signal generator (20), an energy source(22), a second control means (26) and select means (24) adapted to activate said signal generator (20) to generate an interrogation signal (12).

10. Interrogation signal generating device according to claim 9 **characterized in** that said interrogation signal (12) is a radio-wave signal.

11. Interrogation signal generating device according to claim 9 or 10 **characterized in** that said select means (24) comprises a predetermined number of activation buttons (28,30,32,34), wherein each of these buttons represents at least one working parameter of said medical implant.

12. Interrogation signal generating device according to claim 11 **characterized in** that one of said buttons represents the overall status of all working parameters.

Fig 1



# INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 98/02155

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC6: A61N 1/37
According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI

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[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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| Date of the actual completion of the international search | Date of mailing of the international search report |
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| 23 March 1999 | 26 -03- 1999 |
| Name and mailing address of the ISA<br>Swedish Patent Office<br>Box 5055, S-102 42 STOCKHOLM<br>Facsimile No. +46 8 666 02 86 | Authorized officer<br>Karin Säfsten<br>Telephone No. +46 8 782 25 00 |

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International application No.
PCT/SE 98/02155

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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